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Name of Applicant, Assignee or
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5/22/01
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Our Case No. 10716/25

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lewin *et al.*

Serial No.: 09/640,636

Filing Date: August 17, 2000

For: NOVEL HEMATOPOIETIC REGULATORY FACTORS AND METHODS OF USE THEREOF

Examiner Alexander H. Spiegler

Group Art Unit No.: 1656

RESTRICTION RESPONSE

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Responsive to the Official Action of March 20, 2001, Applicants elect, with traverse, Group I, claims 1 – 12, 15 – 18, 21, and 54 - 56.

The Office has restricted the present application into Groups as follows:

I. Claims 1-12, 15-18, 21, and 54-56 drawn to methods of assessing hematopoietic status in a subject, isolated nucleic acids *[sic]* molecules, vectors, host cells, and kits, classified in class 536, subclass 23.1 and class 435, subclass 6, for example.

II. Claims 13-14, drawn to methods of treating a hematopoietic disorder in a subject, classified in class 514, subclass 2, for example.

III. Claims 19, 22-23, drawn to purified polypeptide encoded by a polynucleotide and a method to detect the presence of a polypeptide, classified in class 530, subclass 300, for example.

IV. Claim 20, drawn to an antibody that binds to a polypeptide, classified in class 530, subclass 378.1, for example.

V. Claim 24, drawn to a method of modulating the activity of a polypeptide, classified in class 435, subclass 4, for example.

VI. Claism 25-26, drawn to methods of promoting migration of a hematopoietic stem cell, classified in class 435, subclass 4, for example.

VII. Claims 27-31, drawn to methods of inhibiting proliferation or differentiation of a hematopoietic stem cell, classified in class 435, subclass 4, for example.

VIII. Claim 32, drawn to a method of identifying an agent that modulates hematopoiesis using a polypeptide, classified in class 435, subclass 4, for example.

IX. Claim 33, drawn to a method of identifying an agent that modulates hematopoiesis using a hematopoietic stem cell, class undertminable, subclass undertminable.

X. Claims 34-36, 42-43, drawn to a chimeric polypeptide comprising a chemokine and a hematopoietic modulating sequence, and a method for detecting the polypeptide, classified in class 530, subclass 300, for example.

XI. Claims 37-40, drawn to isolated nucleic acids, vectors, and host cells, encoding a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 536, subclass 23.1, for example.

XII. Claim 41, drawn to an antibody that binds to a chimeric polypeptide comprising a chemokine and a hematopoietic modulating sequence, and a method for detecting the polypeptide, classified in class 530, subclass 378.1, for example.

XIII. Claim 44, drawn to a method of modulating the activity of a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

XIV. Claims 45-46, drawn to methods of promoting migration of a hematopoietic stem cell with the polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

XV. Claim 52, drawn to a method of identifying an agent that modulates hematopoiesis using a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

XVI. Claim 53, drawn to a method of identifying an agent that modulates hematopoiesis using a hematopoietic stem cell and a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

Applicants elect, with traverse, Group I, claims 1 – 12, 15 – 18, 21, and 54 - 56.

Restriction is only proper if the identified groups are independent or distinct. The burden is on the Office to provide reasons and/or examples to support its conclusion that the identified groups are independent or distinct. M.P.E.P. § 803.

The Office asserts:

> . . . each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single [emphasis added by The Office] amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single [emphasis added by The Office] nucleic acid sequences *[sic]* (See MPEP 803.04).

With regards to this assertion, Applicants note that they are obligated to list all sequences separately with distinct SEQ ID Numbers: ". . .each sequence disclosed in the application appear separately in the 'Sequence Listing' with each sequence further being assigned a sequence identification number, referred to as 'SEQ ID NO.' [. . .] The requirement for sequence identification numbers, at a minimum, requires that each sequence be assigned a different number for purposes of identification."(M.P.E.P § 2422.03).

Most importantly, however, is the regulation embodied in M.P.E.P. § 803.04, as The Office has quoted to the Applicants (see Office Action, pages 4 and 5). M.P.E.P. § 803.04 is very clear: the Office allows Applicants to claim up to 10 independent sequences [emphasis added]:

> . . . the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.*[. . .] up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." (M.P.E.P. § 803.04).

The simple enumeration of nucleotide sequences is not grounds for restriction. In light of this, the Applicants have presented only two nucleotide (SEQ ID NOS:1 and 3) and four polypeptide (SEQ ID NOS:2, 4-6) sequences to be examined in the claims, a total that is significantly less than the ten permitted by the Commissioner. Inspection of SEQ ID NOS:3-5 reveals that one polynucleotide sequence, SEQ ID NO:3, encodes the three polypeptide sequences of SEQ ID NOS:4 and 5; likewise, SEQ ID NOS:1, 2 and 6 are closely related, since polynucleotide SEQ ID NO:1 encodes polypeptides SEQ ID NOS:2 and 6. As stated in M.P.E.P. § 803.04, "nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions." Thus the restriction of SEQ ID NOS:4 and 5 from SEQ ID NO:3, and that of SEQ ID NOS:2 and 6 from SEQ ID NO:1 is improper. The restriction is respectfully requested to be withdrawn.

Finally, inclusion of the sequences in the application is necessary to make and carry out the invention. For example, to assess the hematopoietic status of a subject, the method comprises comparing the expression of 25 or more of the nucleic acid sequences (Claim 4). The

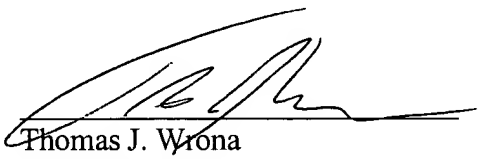
written description manifests that a plurality of sequences are most effective in carrying out the invention.

The Office has characterized the relationship between Groups I - XVI as "drawn on patentably distinct Groups as drawn to multiple SEQ ID Numbers." The Office provides no explanations or examples and fails to cite an appropriate M.P.E.P. reference. As noted in the paragraph above, the simple enumeration of nucleotide sequences is not grounds for restriction (M.P.E.P. § 803.04).

Regarding Groups I - XVI, the Office has failed to characterize the relationship between these groups. No section of the M.P.E.P. has been cited. No basis for determining the distinctness or independence of these groups has been provided, nor any reasons or examples.

Applicants submit that the Office has not met the necessary burden in order to sustain the Restriction Requirement. Withdrawal is therefore respectfully requested.

Respectfully submitted,



Thomas J. Wrona
Registration No. 44,410
Agent for Applicants

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200